

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To: RYAN KROMHOLZ & MANION, S.C. P.O. BOX 26618 MILWAUKEE, WI 53226-0618

Date of mailing (day/month/year)	22 MAR 2010
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Applicant's or agent's file reference 21051-PCT	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US 09/05772	International filing date (day/month/year) 22 October 2009 (22.10.2009)
Applicant MIRAMAR LABS, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: <div style="text-align: right; padding-right: 20px;">Lee W. Young</div> PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 21051-PCT	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 09/05772	International filing date (<i>day/month/year</i>) 22 October 2009 (22.10.2009)	(Earliest) Priority Date (<i>day/month/year</i>) 22 October 2008 (22.10.2008)
Applicant MIRAMAR LABS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 15

☐ as suggested by the applicant.

☒ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/05772

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 4-10 and 14-19
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

-- See extra sheet ---

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-3

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/05772

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61H 1/00 (2010.01)

USPC - 601/2

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

USPC : 601/2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC: 601/1, 15

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 Pubwest (USPAT, PGPUB, JPO, EPO), Google: Applicator, skin, tissue, energy, microwave, emitter, bio-barrier, dermal, conductivity, permeable, loss tangent, permittivity.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/0050083 A1 (Marchitto et al.) 13 December 2001 (13.12.2001) the entire document especially, para [0013], [0110], [0132] and [0134].	1, 3/1
Y		2, 3/2
Y	US 5,097,846 A (Larsen) 24 March 1992 (24.03.1992) the entire document especially, col 14, ln 64 through col 15, ln 30 and Figures 22-24.	2, 3/2
Y	US 6,334,074 B1 (Spertell) 25 December 2001 (25.12.2001) the entire document especially, col 7, ln 49-53 and Figure 1.	2, 3/2
A	US 2007/0255355 A1 (Altshuler et al.) 01 November 2007 (01.11.2007) the entire document.	1-3
A	US 2006/0112698 A1 (Cazzini et al.) 01 June 2006 (01.06.2006) the entire document.	1-3

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

26 February 2010 (26.02.2010)

Date of mailing of the international search report

22 MAR 2010

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/05772

Continuation of Box No. III, Observations where unity of invention is lacking:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group 1 (Claims 1-3) is drawn to a sytem to apply energy to a targeted tissue region comprising an applicator with an energy emitter, and a tissue applicator interface utilizing a bio-barrier system.

Group 2 (Claims 11-13) is drawn to a sytem to apply energy to a targeted tissue region comprising an applicator with an energy emitter, a cooling plate, an applicator controller and sensor, a console, and a special purpose cable system coupling the applicator to the console.

The inventions listed as Groups 1-2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the Group 1 claims is a tissue applicator interface utilizing a bio-barrier system; not required by the claims of Group 2.

The special technical feature of the Group 2 claims is an elongated member, a cooling plate, an applicator controller and sensor, a console, and a special purpose cable system coupling the applicator to the console; not required by the claims of Group 1.

The shared technical feature of an applicator with an energy emitter is anticipated by US 2005/0080359 A1 to Zhao et al. (hereinafter Zhao). Zhao teaches an applicator with an energy emitter (Abstract; Fig. 2; para[0034]).

None of these technical features are common to the other groups, nor do they correspond to a special technical feature in the other groups. Therefore, unity of invention is lacking.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: RYAN KROMHOLZ & MANION, S.C.
P.O. BOX 26618
MILWAUKEE, WI 53226-0618

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) **22 MAR 2010**

Applicant's or agent's file reference
21051-PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 09/05772

International filing date (day/month/year)

22 October 2009 (22.10.2009)

Priority date (day/month/year)

22 October 2008 (22.10.2008)

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A61H 1/00 (2010.01)

USPC - 601/2

Applicant MIRAMAR LABS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion

26 February 2010 (26.02.2010)

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/05772

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

a. (means)

- ☐ on paper
☐ in electronic form

b. (time)

- ☐ in the international application as filed
☐ together with the international application in electronic form
☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/05772

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 4-10 and 14-19

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4-10 and 14-19 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 4-10, 14-19 are unsearchable as they are improper multiple dependent claims in accordance with PCT Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 4-10 and 14-19

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 09/05772

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- ☐ complied with
- ☒ not complied with for the following reasons:

Group 1 (Claims 1-3) is drawn to a system to apply energy to a targeted tissue region comprising an applicator with an energy emitter, and a tissue applicator interface utilizing a bio-barrier system.

Group 2 (Claims 11-13) is drawn to a system to apply energy to a targeted tissue region comprising an applicator with an energy emitter, a cooling plate, an applicator controller and sensor, a console, and a special purpose cable system coupling the applicator to the console.

The inventions listed as Groups 1-2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the Group 1 claims is a tissue applicator interface utilizing a bio-barrier system; not required by the claims of Group 2.

The special technical feature of the Group 2 claims is an elongated member, a cooling plate, an applicator controller and sensor, a console, and a special purpose cable system coupling the applicator to the console; not required by the claims of Group 1.

The shared technical feature of an applicator with an energy emitter is anticipated by US 2005/0080359 A1 to Zhao et al. (hereinafter Zhao). Zhao teaches an applicator with an energy emitter (Abstract; Fig. 2; para[0034]).

None of these technical features are common to the other groups, nor do they correspond to a special technical feature in the other groups. Therefore, unity of invention is lacking.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts
- ☒ the parts relating to claims Nos. 1-3

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 09/05772

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 3/2	YES
	Claims	1, 3/1	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-3	NO
Industrial applicability (IA)	Claims	1-3	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1 and 3/1 lack novelty under PCT Article 33(2) as being anticipated by US 2001/0050083 A1 to Marchitto et al. (hereinafter 'Marchitto').

Regarding claim 1, Marchitto discloses a system to apply energy to a targeted tissue region (para [0013], Figs. 1, 2, 8, 17-19) comprising an applicator (30) including an applicator interior (Figs. 1 and 19) carrying at least one energy emitter (para [0110] and Figs. 1, 2 and 19, laser), and a tissue-applicator interface (68) sized and configured to be attached to the applicator for use in operative association with the energy emitter (para [0131]-[0134], [0141]; Figs. 8, 17-19) and to be detached from the applicator after use (para [0139], container unit is disposable), the tissue-applicator interface comprising a bio-barrier system (82) that, when the tissue-applicator interface is attached to the applicator, isolates the applicator interior from contact with physiologic liquids in the targeted tissue region (para [0134]; Fig. 17, lens 84), the bio-barrier system including a first bio-barrier component having a prescribed conductivity to pass energy from the energy emitter to the targeted tissue region without substantial interference and loss of power (para [0134]).

Regarding claim 3/1, Marchitto further discloses wherein the tissue-applicator interface includes a tissue acquisition chamber (para [0139]; Fig. 17, receptacle 82) that acquires tissue in the targeted tissue region for application of energy in response to negative pressure generated by an external source and conveyed into the tissue acquisition chamber (para [0142] and Figs. 18 and 19) and wherein the bio-barrier system includes a second bio-barrier component separate from the first bio-barrier component (para [0142], plug 70), the second bio-barrier being, substantially permeable to air to balance negative pressure between the tissue acquisition chamber and the applicator interior when the tissue-applicator interface is attached to the applicator (para [0142]-[0143], wherein the plug 70 is permeable to gas when perforated while the receptacle 82 is under vacuum), the second bio-barrier component also being substantially impermeable to liquids to isolate the applicator interior from contact with physiologic liquids in the targeted tissue region while balancing the negative pressure (para [0142] and Figs. 18 and 19, wherein the second bio-barrier plug 70 which is impermeable to liquids and gases when in air tight state).

Claims 2 and 3/2 lack an inventive step under PCT Article 33(3) as being obvious over Marchitto taken with US 6,334,074 B1 to Spertell and US 5,097,846 A to Larsen.

As per claim 2, Marchitto discloses the system according to claim 1, but fails to specifically disclose wherein the prescribed conductivity comprises a loss tangent of not greater than 0.1 in accordance with the equation relation claimed. Spertell discloses a similar system for applying energy to a targeted tissue region comprising an applicator (10) with a microwave energy emitter and a disposable single-use tissue-applicator interface (80) to be attached to the applicator. Further, Larsen discloses a bio-barrier component (400) for use with a microwave emitter, the bio-barrier component having a conductivity comprising a loss tangent of not greater than 0.1 (col 14, ln 64 - col 15, ln 30). In light of Marchitto and Spertell, it would have been obvious to one of ordinary skill in the art to utilize a bio-barrier system, such as that disclosed in Marchitto, with a microwave energy applicator, such as that disclosed in Spertell, in order to protect the internal components of the applicator from the various fluids at the application site, utilizing a bio-barrier component with a low loss tangent for microwave energy such as that disclosed by Larsen to effectively communicate as much of the energy through the barrier as possible.

Regarding claim 3/2, in the combination of Marchitto, Spertell and Larsen, Marchitto further discloses wherein the tissue-applicator interface includes a tissue acquisition chamber (para [0139]; Fig. 17, receptacle 82) that acquires tissue in the targeted tissue region for application of energy in response to negative pressure generated by an external source and conveyed into the tissue acquisition chamber (para [0142] and Figs. 18 and 19) and wherein the bio-barrier system includes a second bio-barrier component separate from the first bio-barrier component (para [0142], plug 70), the second bio-barrier being, substantially permeable to air to balance negative pressure between the tissue acquisition chamber and the applicator interior when the tissue-applicator interface is attached to the applicator (para [0142]-[0143], wherein the plug 70 is permeable to gas when perforated while the receptacle 82 is under vacuum), the second bio-barrier component also being substantially impermeable to liquids to isolate the applicator interior from contact with physiologic liquids in the targeted tissue region while balancing the negative pressure (para [0142] and Figs. 18 and 19, wherein the second bio-barrier plug 70 which is impermeable to liquids and gases when in air tight state).

Claims 1-3 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.